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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,379	01/23/2004	Albert Zorko Abram	021706-000420US	7565

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,379	ABRAM ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,10-12,14-33,35-37 and 65-88* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 75-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 14-33, 35-37, 65-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 01/26/06 and Supplemental Amendments and Remarks filed on 03/02/06. Claims 1, 3-4, 36, 67 and 68 are amended, claim 2 has been cancelled and new claims 67-88 are added. Accordingly, claims 1, 3-5, 10-12, 14-33, 35-37 and 65-88 are pending, of which claims 11-12 are withdrawn.

Newly submitted claims 75-88 are directed to an invention that is independent or distinct from the invention originally elected. Applicant elected inventions of Group I (the composition claims) in a telephonic interview on 04/22/05, Accordingly the newly submitted claims 75-88, drawn to a method of treating is considered non-elected.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 75-88 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-5, 10, 14-33, 35-37 and 65-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al (20030118511 A1) in view of Klein et al (5,446,028).

Jones et al teach corticosteroid- containing pharmaceutical compositions comprising a corticosteroid, a quick-break foaming agent, a propellant and a buffering agent. The said composition is applied to the skin site as a foam, which is a thermophobic quick-break foam (see [0006] and [0007]). The quick-break foaming agent comprises an aliphatic alcohol, in an amount of from 40-90%, water in an amount of from 10-40%, at least one fatty alcohol in an amount of from 0.5 to 10% and a surface active agent in an amount of from 0.1 to 15% w/w (see [0008]).

Jones also discloses that the aliphatic alcohol may be selected from ethanol, methanol, isopropanol, etc, or mixtures thereof (see [0014]). The fatty alcohol may be selected form cetyl alcohol, stearyl alcohol, or mixtures of the two, known as octadecan-1-ol (see [0013]). The surface active agent may be selected form ethoxylated sorbitan stearate, palmitate, oleate or mixtures thereof. Suitable surfactant is polysorbate 60 ([0015]). The propellant may be selected form butane, propane, ethane, etc, which is present in an amount of 3-30 or preferably from 3-5% w/w (see [0016]). The composition may contain a buffering agent and the desirable pH level is from 3.0 to 6.0, and most preferably from 4.0 to 5.0 ([0021]). The composition may also comprise a humectant such as propylene glycol, glycerine, sorbitol, etc, present in an amount of from 0.5 to 3.0% w/w (see [0017]).

Jones et al teach that corticosteroids, or a mixture of corticosteroids, are present in the formulation from about 0.01 to 1.0% w/w (see [0018]-[0020] and claim 8). It is also disclosed that in use, the composition is sprayed, producing a semi-solid (i.e. foam or mousse) that is suitable for the topical application to skin or scalp. On application, heat from the skin causes the foam to break down to liquid form (see [0025]). Jones exemplifies a formulation in a table disclosed under section [0028], which discloses amounts of each ingredient. For example the

formulation comprises 57.79% ethanol and 33.69% water. Thus the ratio of ethanol : water is 1.7:1, the same as the requirements of instant claim 15.

Jones discloses corticosteroid as the active agent, but does not disclose other active agents suitable for inclusion in the said foam formulation.

Klein et al teaches compositions and method for the treatment of acne including a peroxide and an antibiotic selected from the lincomycin family of antibiotics (see abstract). Exemplary antibiotics include lincomycin and clindamycin and their acceptable slats such as hydrochlorides and phosphates (col. 2, lines 33-38).

Examples 1-6 and 12-13 show various dosage forms comprising clindamycin and benzoyl peroxide, with examples 5 and 12-13 disclosing clindamycin phosphate. Example 12 discloses an aerosol spray comprising from 0.1 to 5% clindamycin phosphate and from 1 to 20% benzoyl peroxide. The suitable pH range for the said topical formulations is from 4.6 to 5.7 (see col. 8, lines 7-17 and claims 3 and 8).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the quick-breaking foaming formulations of Jones et al comprising an active agent with the acne treating formulations of Klein et al comprising clindamycin phosphate and benzoyl peroxide with a reasonable expectations of successfully preparing an efficient and stable foam for treating skin disorders such as acne.

Response to Arguments

Applicant's arguments filed on 01/26/06 and 03/02/06 have been fully considered but they are not persuasive.

Applicant argues that there is no suggestion or motivation to modify the references. Applicant states that Jones teaches delivery of corticosteroids but does not disclose delivery of antibiotics. Applicant also states that Klein teaches a composition of benzoyl peroxide and an antibiotic in various forms such as an aqueous gel form, but does not teach foams. Applicants statements are correct, however the arguments regarding their combination are not persuasive. Jones is teaching a quick-breaking foam formulation comprising an active agent, propellant, pH adjusting agents and the quick-breaking agent. The said topical formulations are used for treating skin disorders. Klein teaches that antibiotics such as clindamycin are effective for treating skin disorders such as acne. Klein also discloses that benzoyl peroxide can be added for increased effects. One of ordinary skill in the art is motivated to substitute one active agent for another in a given dosage form or base for added options for the user and/or a better application. Applicant has not shown a criticality of a foam formulation comprising clindamycin or any other antibiotic. It is also not shown why one of ordinary skill would not be successful in substituting an antibiotic for a corticosteroid. It is well known in the art to use the same dosage form for various active agents.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
April 14, 2006

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER